DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

466 Fernandez Juncos Avenue
Puerta De Tierra
San Juan, Puerto Rico 00901-3223

October 16, 2000

WARNING LETTER
SJN-01-01

CERTIFIED MAIL
Return Receipt Requested

Mr. Jose Gonzalez-Freyre, President
Pan American Grain Mfg. Co., Inc.
Claudia Street #9 Amelia Industrial Park
Guaynabo, Puerto Rico 00968

Dear Mr. Gonzalez-Freyre:

An investigation of your medicated feed mill located at Claudia Street #9 Amelia Industrial Park, Guaynabo, Puerto Rico, conducted by a Food and Drug Administration investigator on August 24, 25 and 30, 2000 found significant deviations from Current Good Manufacturing Practice (GMP) regulations for Medicated Feeds (Title 21 CODE OF FEDERAL REGULATIONS, Part 225). Such deviations cause feeds being manufactured at this facility to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

Our investigation found the following deviations from the Current Good Manufacturing Practice regulations:

1. Failure to conduct periodic potency assays for drug components on representative samples of the "16% Custom Formula Medicinado" to ensure the feed conforms to specified requirements of strength in accordance to 21 CFR 225.158.

2. Failure to calibrate your production weighing scales in accordance to 21 CFR 225.130.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations.

You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory sanctions. These sanctions include, but are not limited to, seizure and/or injunction.

For your information, a review of the product label for "16% Custom Formula Medicinado" revealed several issues that we would like to bring to your attention. First,

the product label does not bear a statement of the approved indications nor the directions for use described in 21 CFR 558.355(f) as required by 21 CFR 201.5. Second, the product label must also bear the following warning statements:

"Do not allow horses or other equines access to formulations containing monensin. Ingestion of monensin by equines has been fatal."[21 CFR 558.355 (6)] and [21 CFR 558.355 (8)]

"Monensin medicated cattle feed is safe for use in cattle only. Consumption by unapproved species may result in toxic reactions." [21 CFR 558.355 (7)(i)] and [21 CFR 558.355 (8)]

"Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result." [21 CFR 558.355 (7)(v)] and [21 CFR 558.355 (8)]

If your product is distributed solely within the Commonwealth of Puerto Rico, you may translate the above statements into Spanish as described in 21 CFR 201.15 (c)(1).

Please notify the San Juan District office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of these or similar violations.

Your reply should be sent to the Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, Puerto Rico, 00901-3223,
Attention: Steven B. Barber, Acting Compliance Officer.

Sincerely,

Wayne Matthews for
Mildred R. Barber
District Director